

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6221395	B1	2001-04-24	Jagotec AG	
	2	6465011	B2	2002-10-15	Abbot Laboratories	
	3	6558699	B2	2003-05-06	SmithKline Beecham Corporation	
	4	4772605		1988-09-20	Naik et al.	
	5	5554789		1996-09-06	Carganico et al.	
	6	4925676		1990-05-15	Warner-Lambert Company	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	MI/43212-US-1

1	20080051411	A1	2008-02-28	Cink, et al.	
2	20060280790	A1	2006-12-14	Ju, et al.	
3	20060280791	A1	2006-12-14	Ju, et al.	
4	20070264334	A1	2007-11-15	Ju, et al.	
5	20070185199	A1	2007-08-09	Ju, et al.	
6	20070148234	A1	2007-06-28	Ju, et al.	
7	20070128278	A1	2007-06-07	Ju, et al.	
8	20080152714	A1	2008-06-28	Gao, et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² ^j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	96/19962	WO		1996-07-04	Rosenberg, et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

2	96/19963	WO		1996-07-04	Rosenberg, et al.		<input type="checkbox"/>
3	98/22094	WO		1998-05-28	Maul, et al.		<input type="checkbox"/>
4	99/12526	WO		1999-03-18	Alza Corporation		<input type="checkbox"/>
5	99/45887	WO		1999-09-16	Pillay, et al.		<input type="checkbox"/>
6	01/34119	WO		2001-05-17	Abbott Laboratories		<input type="checkbox"/>
7	02/026214	WO		2002-04-04	Solvay Pharmaceuticals B.V.		<input type="checkbox"/>
8	05/013940	WO		2005-02-17	Vanderbist, et al.		<input type="checkbox"/>
9	05/046662	WO		2005-05-26	JJ Pharma, Inc.		<input type="checkbox"/>
10	06/135480	WO		2006-12-21	Abbott Laboratories		<input type="checkbox"/>
11	0240904	EP		1992-07-01	Goertz, et al.		<input type="checkbox"/>
12	0337256	EP		1992-11-19	Klimesch, et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

	13	0240906	EP		1991-05-02	Klimesch, et al.		<input type="checkbox"/>
	14	0358105	EP		1994-03-02	Klimesch, et al.		<input type="checkbox"/>
	15	0358108	EP		1992-04-15	Plath, et al.		<input type="checkbox"/>
	16	1157690	EP		2006-08-02	Biovail Laboratories International		<input type="checkbox"/>
	17	1159419	EP		2005-08-03	Dawson, et al.		<input type="checkbox"/>
	18	1829541	EP		2007-09-05	Rosenberg, et al.		<input type="checkbox"/>
	19	19536394	DE		1997-04-03	BASF AG		<input type="checkbox"/>
	20	19629753	DE		1998-01-29	BASF AG		<input type="checkbox"/>
	21	19731277	DE		1999-01-28	Susskind-Schwendi, et al.		<input type="checkbox"/>
	22	96/016016	WO		1996-05-30	Laboratorios Menarini S.A. et al.		<input type="checkbox"/>
	23	1621200	EP		2006-02-01	Fournier Laboratories Ireland Limited		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Arzneimittel-Forschung 26, 885-909 (1976) - see p. 887	<input type="checkbox"/>
	2	BASTIN et al., Organic Process Research and Development, Vol. 4, pp. 427-435 (2000)	<input type="checkbox"/>
	3	FEELY, L.C. & DAVIS S.S., The Influence of polymeric excipients on drug release from hydroxypropylcellulose matrices," International Journal of Pharmaceutics, Vol. 44, pp. 131-139 (1998)	<input type="checkbox"/>
	4	FIEDLER, H.B., Lexikon der Eijsstoffe fir Pharmazie, Kosmetik, and Angrenzende Gebete, 4th Ed., Aulendorf: ECV-Editio-Cantor-Verlag (1996)	<input type="checkbox"/>
	5	FIKENTSCHER, H., Cellulose-Chemie, Vol. 13, pp. 58-64 and 71-74 (1932)	<input type="checkbox"/>
	6	FORD, J.L., Pharma. Acta. Hely., Vol. 61, pp. 69-88 (1986)	<input type="checkbox"/>
	7	FROHOFF-HULAMANN, M.A., et al, "Aqueous ethyl cellulose dispersions containing plasticizers of different water solubility and hydroxypropylmethylcellulose as coating material for diffusion pellets II: properties of sprayed films," Eur. J. of Pharm. & Biopharm., Vol. 48(1), pp. 65-75 (1999)	<input type="checkbox"/>
	8	FROHOFF-HULAMANN, M.A., et al, "Aqueous ethyl cellulose dispersions containing plasticizers of different water solubility and hydroxypropylmethylcellulose as coating material for diffusion pellets I: Drug release rates from coated pellets," Int'l J. of Pharm., Vol. 177(1), pp. 69-82 (1999)	<input type="checkbox"/>
	9	Guidance for Industry SUPAC-MR: Modified Release Solid Oral Dosage Forms, U.S. Dept. of Health and Human Serv., FDA, CDER.CMC (8): 1-B-6 (1997)	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

10	GURRIERI, J., Antilipidemic Drugs, <i>Arzneim-Forsch (Drug Res.)</i> , Vol. 26(5), pp. 890-894 (1976)	<input type="checkbox"/>
10	Overview of acrylic polymer - Eudragit	<input type="checkbox"/>
12	RAO, K.V.R., et al., Zero-Order Release of a Very Soluble Drug From Swelling and Erosion Controlled polymeric Matrices, <i>Contr. Int. Techol. Pharm.</i> 5th, Vol. 5, pp. 242-249 (1989)	<input type="checkbox"/>
13	REMINGTON, <i>The Science and Practice of Pharmacy</i> , 19th ed. Table of Contents (1995)	<input type="checkbox"/>
14	SUCKER, H., <i>Pharmazeutische Technologie</i> , Thieme-Verlag, Stuttgart (1978)	<input type="checkbox"/>
15	TALUKDAR, M.M., et al., Comparative study of xanthan gum and hydroxypropylmethylcellulose as matrices for controlled-release drug delivery I. Compaction and in vitro drug release behavior, <i>Int'l J. of Pharmaceutics</i> , Vol. 129, pp. 233-241 (1996)	<input type="checkbox"/>
16	USP Volume 25, Ch. 776 (2002)	<input type="checkbox"/>
17	XU, D., et al., Influence of ionic strength on drug release from HPMC hydrogel matrix, <i>Chinese Pharm. J.</i> , Vol. 23(1), pp. 7-9 (2003)	<input type="checkbox"/>
18	YE, et al., Application of neural network in predicting release of insoluble drugs from HPMC matrix tablets,	<input type="checkbox"/>
19	TOMA, K., <i>Pharm. Ind.</i> , Vol. 51, pp. 98-101 (1989)	<input type="checkbox"/>
20	SONG, H., et al., Preparation of the Traditional Chinese Medicine Compound Recipe Heart-Protecting Mud pH Dependent Gradient-Release Pellets, <i>Drug Development and Industrial Pharmacy</i> , 28(10), pp. 1261-1273 (2002)	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

21	CARSTENSEN, J.T., et al., Drug Stability: Principles and Practices, Informa HealthCare, 3rd Edition, p. 316 (2000)	<input type="checkbox"/>
22	BERGE et al., Pharmaceutical Salts, J. Pharm. Sci, Vol. 66, No. 1, pp. 1-19 (1977)	<input type="checkbox"/>
23	MARGUERY et al., Comparison of the DNA Damage Photoinduced by Fenofibrate and Ketoprofen, Two Phototoxic Drugs of Parent Structure, Photochemistry and Photobiology, 68(5), pp. 679-684 (1998)	<input type="checkbox"/>
24	WULFURT et al., Inhibition of Membrane-Bound Hepatic 3-hydroxy-3-methyl glutaryl-CoA Reductase as the Consequence of Altered Membrane Fluidity, Artery, 9(2), pp. 120-131 (1981)	<input type="checkbox"/>
25	WALKING et al., Decision Analysis in Drug Product Development, Drug Cosmetic Industry, 112(3), p. 39 (1973)	<input type="checkbox"/>
26	DUESEL et al., Substituted Xanthines, Journal of the American Pharmaceutical Association, Vo., 43, Issue 10, page 619 (1954)	<input type="checkbox"/>
27	DUESEL et al., Choline Theophyllinate a New Stable Theophylline Derivative of Enhanced Solubility, Int. Rec. Med. Gen. Pract. Clin., Vol. 167, pp. 245-247 (1954)	<input type="checkbox"/>
28	MORRIS et al., An Integrated Approach to the Selection of Optimal Salt form for a New Drug Candidate, Int. J. of Pharm., Vol. 105, pp. 209-217 (1994)	<input type="checkbox"/>
29	IMPAX LABORATORIES, INC., Paragraph IV Patent Certification Notice, January 26, 2010	<input type="checkbox"/>
30	LUPIN LTD., Paragraph IV Certification, February 9, 2010	<input type="checkbox"/>
31	MYLAN PHARMACEUTICALS, Paragraph IV Certification, March 9, 2010	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2010-03-31
First Named Inventor	Jorg Rosenberg et al.
Art Unit	1621
Examiner Name	Katakam, Sudhakar
Attorney Docket Number	M/43212-US-1

32	WATSON LABORATORIES, INC. - FLORIDA, Paragraph IV Certification, March 12, 2010	<input type="checkbox"/>
33	Merck Manual, Vol. 1, pp. 771-780 (1987)	<input type="checkbox"/>
34	www.americanheart.org/presenter.jhtml?identifier=4600	<input type="checkbox"/>
35	Actavis Elizabeth LLC, Paragraph IV Certification, April 5, 2010	<input type="checkbox"/>
36	Frohoff-Hulmann, M.A. et al., Aqueous ethyl cellulose dispersions containing plasticizers of different water solubility and hydroxypropylmethylcellulose as coating material for diffusion pellets II: properties of sprayed films, Eur. J. of Pharm. & Biopharm., Vol. 48(1), 65-75 (1999)	<input type="checkbox"/>
37	Fournel et al., Xenobiotica, 17, 4, 445-457 (1987)	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.